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10/080,749	02/22/2002	Bo Johnson	30275-00006	8409

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,749

Applicant(s)

JOHNSON, BO

Examiner

Jennifer K. Michener

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32, 38-41 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-32, 38-41, 43-44, 48-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Objections

1. The objections to claims 38-41 and 44 have been withdrawn based on Applicant's amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 29-32 and 38-41, 43-44, 48-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Examiner maintains the rejection of the previous office action.

Canceled claim 42 has been removed from this rejection.

New claims 48-52 have been added to this rejection.

Based on Applicant's amendments, the following new 112, 1st rejections are made:

5. Claims 29, 30, 32, 38-41, 44, and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new limitation regarding the pH being generally under 4.0 appears to be new matter. The specification provides broad requirements for a "low" pH. In coating solution example 3, the specification requires an exemplary pH for the hyaluronic acid solution of 2.3. On page 14, Applicant states that all of the described solutions employ a pH of 2.0-4.0 and that other solutions may use a pH that can range between 1 and 6.5. Broadly claiming "generally under 4.0" is new matter. The specification has basis for a pH of 2.3, or a pH of 2.0-4.0, or a pH of 1-6.5. As written, claim 29, for example, is open to a pH of below 2.0, even below 1, as allowed in other solutions, which is new matter. Regarding claim 30, Applicant has combined embodiments in a manner that was not intended by the specification. Now that "under 4.0" has been added to the independent claim, the dependent claim, which used to require the other embodiment of "1-6.5" (and has since been narrowed to a range of 1-3, for which there is no teaching) is a combination that was not foreseen at the time the application was filed.

Claim 32 contains the same new matter as claim 29. The only example of a suitable pH for a method of applying one solution containing both hyaluronic acid and heparin is one in which the pH of both solutions is 2.3.

Examiner is unable to find basis in the originally-filed disclosure for the use of analogues of hyaluronic acid, as is required by claims 32 and 52.

Claims 50 and 51 require dissolving the hyaluronic acid solution or the solution of hyaluronic acid and heparin into a solution of sodium chloride. However, there is no basis for this limitation. The instant specification discusses only the dissolution of heparin into an NaCl solution (page 10).

Based on Applicant's amendments, the following new 112, 2nd rejections are made:

6. Claims 29, 31, 32, 38-41, 43, 44, 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "generally" regarding the pH being under 4.0 is unclear. It is not clear whether the term requires that the pH be under around 4.0 or if the term requires the solution to usually be under 4.0, allowing for some variation. The metes and bounds of the claim cannot be ascertained.

Claim Rejections - 35 USC § 102

7. The rejection of claims 29, 32, 41, and 44 under 35 U.S.C. 102(e) as being anticipated by Hossainy (US2002/0087123 A1) has been withdrawn based on Applicant's amendments in favor of incorporation into the 103 rejection, below.

8. The rejections of claims 29, 30, 32, 41, 42, and 44 under 35 U.S.C. 102(e) as being anticipated by Burns et al. has been withdrawn based on Applicant's amendments in favor of incorporation into the 103 rejection, below.

Claim Rejections - 35 USC § 103

The following rejections have been reformatted to incorporate the limitations of the amended/newly-added claims:

9. Claims 29-32, 38-41, 43-44, 48-49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al.

Hossainy teaches coating blood-contacting medical device surfaces with heparin and hyaluronic acid (abstract; P25). The hyaluronic acid acts as an adhesion-enhancing substance for the heparin and therefore "bonds" to the substrate. The materials are applied in solution. Adhesion-enhancing substances may be applied as a primer in the method of Hossainy (P26). There is no teaching in Hossainy of photochemical treatment, so the bonding occurs "without photochemical treatment", as required by the claims.

The substrate of Hossainy may be stainless steel (see, at least, Examples).

Hossainy et al. teach that which is disclosed above, but fails to teach a pH for the coating solutions. It is Examiner's position that selection of a pH would have been within the skill of an ordinary artisan desiring to optimize a coating operation. Heparin

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and hyaluronic acid will be most stable and will form more adherent coatings at specific pH ranges.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the requirement that the heparin be either a low molecular weight heparin, unfractionated, or higher molecular weight heparin, it is Examiner's position that it would have been obvious to an ordinary artisan to select a heparin from one of the molecular weight ranges. Likewise, the weight ranges required for hyaluronic acid would have been optimized by an ordinary artisan depending on the coating properties, such as viscosity, desired by one of ordinary skill in the art. As outlined above, it is well settled that determination of optimum values of cause effective variables is within the skill of one practicing in the art.

It is well-known in the art to lower pH with the addition of an acid, such as hydrochloric acid.

10. Claims 29-30, 32, 38-41, 44, 49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns.

Burns et al. teaches coating fibers, substrates, or mesh with a solution of hyaluronic acid and heparin (abstract; col. 2, line 58; col. 3, line 67-col. 4, line 2; col. 9, line 5). The

hyaluronic acid inherently "bonds" to the substrate as it adheres for later use. There does not appear to be any photochemical treatment in the method of Burns. Burns teaches a pH range of 4.6-5.1, which is merely exemplary, but which meets the limitation of "generally under 4.0" if such a limitation requires a pH of approximately 4.0 or below. Additionally, it is Examiner's position that selection of a pH would have been within the skill of an ordinary artisan desiring to optimize a coating operation for those reasons outlined above.

The substrate of Burns may be polymer fiber, meeting the limitation of claims 41 and 44.

Burns teaches that which is disclosed above, but fails to teach the molecular weight of the heparin or hyaluronic acid. For those reasons outlined above, it is Examiner's position that selection of optimum variables, such as this, would have been within the skill of an ordinary artisan.

It is well-known in the art to lower a pH with the addition of an acid, such as hydrochloric acid.

11. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Hossainy or Burns in view of Shah et al. (6,387,450).

The following rejection is provided as an alternative to portions of the 103 rejections, above.

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Hossainy and Burns teach that which is disclosed above, but fail to teach the molecular weight of hyaluronic acid.

Shah teaches a method of coating metallic or polymeric medical devices, to be used in contact with physiological fluids, with solutions of hyaluronic acid at molecular weights of about 70,000 to about 6 million Daltons (abstract; col. 1; col. 4, lines 5-15).

Since Hossainy, Burns, and Shah teach coating metallic or polymeric medical devices used in contact with body fluids with solutions of hyaluronic acid and Shah teaches suitable molecular weight ranges for such solutions, Shah would have reasonably suggested the use of hyaluronic acid with the molecular weights outlined in his method.

It would have been obvious to one of ordinary skill in the art to use the teachings of Shah in the method of either Hossainy or Burns with the expectation of successful results since their coating methods, substances, and substrates are similar to Shah's. The range of Shah overlaps that of claim 38 and is within the range of "about 7 million Daltons" as claimed by claim 39.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Shah's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Response to Arguments

12. Applicant's arguments filed 1/3/2005 have been fully considered but they are not persuasive.

Applicant argues that the new matter rejection is incorrect because it requires him to prove the absence of something from the specification. He states that photochemical treatment is not required by the specification, so it is clearly not used.

Examiner disagrees.

The negative limitation "without photochemical treatment" is requiring the necessary absence of an element. There is no indication that Applicant was in possession of a method *requiring* the specific absence of such a treatment at the time the application was filed. New matter includes not only the addition of wholly unsupported subject matter, but may also include...the omission of a step from a method" (MPEP 706.03).

Examiner notes that there are an infinite number of method steps not specifically disclosed by Applicant's specification, however, there would be no basis for claim limitations requiring specific exclusion of each of these possibilities.

The arguments regarding the pH requirements have been addressed above in the body of the claim rejections.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

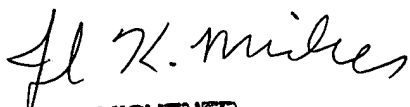
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Tuesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JENNIFER MICHENER
PRIMARY EXAMINER

AU 1762
April 17, 2005